

Original article

Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 10-year results of a prospective, randomized trial

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Abstract

Background: There are few studies of long-term outcomes for either laparoscopic adjustable gastric banding (LAGB) or laparoscopic Roux-en-Y gastric bypass (LRYGB). The objective of this study was to compare outcomes of patients randomly assigned to undergo LAGB or LRYGB at 10 years.

Methods: LAGB, using the pars flaccida technique, and standard LRYGB were performed. From January 2000 to November 2000, 51 patients (mean age 34.0 ± 8.9 years; range 20–49) were randomly allocated to undergo either LAGB ($n = 27$, 5 men and 22 women; mean age 33.3 years; mean weight 120 kg; mean body mass index [BMI] 43.4 kg/m^2) or LRYGB ($n = 24$, 4 men and 20 women; mean age 34.7; mean weight 120 kg; mean BMI 43.8 kg/m^2). Data on complications, reoperations, weight, BMI, percentage of excess weight loss, and co-morbidities were collected yearly. The data were analyzed using Student's *t* test and Fisher's exact test, with $P < .05$ considered significant.

Results: Five patients in the LAGB group and 3 patients in the LRYGB group were lost to follow-up. No patient died. Conversion to laparotomy was performed in 1 (4.2%) of 24 LRYGB patients. Reoperations were required in 9 (40.9%) of 22 LAGB patients and in 6 (28.6%) of the 21 LRYGB patients. At 10-year follow-up, the LRYGB patients had a greater percentage of mean excess weight loss than did the LAGB patients ($69 \pm 29\%$ versus $46 \pm 27\%$; $P = .03$).

Conclusion: LRYGB was superior to LAGB in term of excess weight loss results (76.2% versus 46.2%) at 10 years. However, LRYGB exposes patients to higher early complication rates than LAGB (8.3% versus 0%) and potentially lethal long-term surgical complications (internal hernia and bowel obstruction rate: 4.7%). (Surg Obes Relat Dis 2013;■:00-00.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords :

Lap-Band; Gastric bypass; Long term weight loss; Prospective; randomized study

Obesity epidemic continues to grow worldwide. Surgery remains the only therapy with a long-term effectiveness [1,2]. Laparoscopic adjustable gastric banding (LAGB) was introduced in Europe in 1994 [3,4], and almost

simultaneously laparoscopic Roux-en-Y gastric bypass (LRYGB) was developed in the United States [5]. These operations are increasingly used to induce weight loss and maintenance of weight loss in obese individuals, but results after 10 years are lacking in the international literature. This is an update report at 10 years of a prospective, randomized study of LAGB versus LRYGB in severely obese patients with a body mass index (BMI) > 35 and $< 50 \text{ kg/m}^2$. The 5-year data have been published previously [6].

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Methods

Patients were referred for surgical therapy of obesity and were preoperatively invited to seminars where LAGB and LRYGB were explained in detail. Patients were preoperatively screened for co-morbidities (type 2 diabetes mellitus [T2DM], arterial hypertension, and dyslipidemia). Sleep apnea was diagnosed by routine polysomnography testing. Preoperative patient selection, randomization criteria, causes for exclusion, and the surgical technique have been reported previously [6]. Data on mortality, conversion to an open procedure, postoperative complications leading to reoperation, hospital stay, weight, BMI, decrease in BMI, percentage of excess weight loss, weight regain, and improvement in co-morbidities were analyzed. Both groups were followed-up in the surgeon's office with a dietician counseling every 3 months for the first year and every 6 months for subsequent years. After the first 5 years, patients were invited for an office consultation once per year; otherwise, they were reached by phone. In LRYGB group, patients were screened for nutritional deficiencies with a complete blood work every 6 months for the first 2 years and then yearly. Patients answering the phone consultation were considered present at follow-up. Follow-up is presented as the number of patients followed up divided by the total number of patients eligible for follow-up during each postoperative year. Bypass patients were instructed to take postoperative supplements (vitamin B₁₂ 1000 µg, vitamin A 10,000 UI, and vitamin D 50,000 UI IM monthly; oral multivitamin, iron and calcium, carbonate 1500 mg PO daily) for all of their life; compliance with these recommendations was also recorded. LAGB patient weight loss data were excluded from the study at conversion to any other bariatric procedure. Data of converted patients are presented separately. Band adjustment was performed when clinically indicated and was individually tailored for each patient to obtain weight loss and symptoms of satiety. Inadequate weight loss was defined using the criteria of Halverson and Koehler of <50% excess weight loss (%EWL) [7]. Excess weight was calculated as the difference between patients' weight and the "ideal" weight according to the middle weight of medium frame tables of Metropolitan Life Insurance Company. Weight loss was reported as postoperative weight, postoperative BMI, and %EWL. The %EWL was calculated as follows: $100\% \times (\text{preoperative weight} - \text{postoperative weight}) / (\text{preoperative weight} - \text{ideal weight})$. For each postoperative year, the weights of all patients measured in that year were averaged to calculate the average %EWL and postoperative BMI. Weight regain was evaluated considering the difference in weight, BMI, and %EWL between the lowest weight achieved (2 years after surgery) and data available 10 years postoperatively. Data are expressed as the mean \pm standard deviation, except as otherwise indicated. The data were not examined on an intention-to-treat analysis.

Student's *t* test and Fisher's exact test were used for statistical analysis, with *P* < .05 considered significant. Regarding co-morbidities remission, patients visited in the office were evaluated considering glycated hemoglobin (HbA_{1c}), lipids blood testing, polysomnography, and blood pressure. Discontinuation of medical therapy was also inquired, and if necessary, they were referred to specialist counseling. Patients who could be reached only by phone were asked about reduction or interruption of medical therapy and recent blood test.

The remission of T2DM is defined as a return to normal measures of glucose metabolism (HbA_{1c} <6%; fasting glucose <56 mmol/L) after bariatric surgery in the absence of hypoglycemic medications. The improvement of T2DM is defined as an amelioration of HbA_{1c} and fasting glucose versus baseline in the absence of hypoglycemic therapy or as reduction of diabetes medications.

The remission of arterial hypertension is defined as a systolic blood pressure <140 mm Hg and a diastolic blood pressure <90 mm Hg in the absence of antihypertensive drugs. The improvement of arterial hypertension is defined as reduction of antihypertensive drugs.

The remission of dyslipidemia is defined as normal blood lipid levels in the absence of hypolipidemic drugs (LDL <100 mg/dL; HDL >40 mg/dL; triglycerides <150 mg/dL). The improvement of dyslipidemia is defined as reduction of hypolipidemic drugs.

The remission of sleep apnea is defined as absence of symptoms attested by a normal polysomnography testing.

Surgical techniques of LAGB and LRYGB are described in details in our previous publication [6].

Results

No patient died. One patient who underwent LRYGB required an intensive care unit stay of 40 days during her very long and complicated postoperative recovery period. Five of 27 LAGB patients were lost to follow-up, 1 of which was within the first 5 years. Overall follow-up at 10 years was obtained in 22 of 27 (81.4%) patients who underwent LAGB and in 21 of 24 (87.5%) patients who underwent LRYGB. Of the LAGB patients present at follow-up at 10 years, 12 of 27 (44.4%) were seen in the clinic and 10 of 27 (37%) could be reached only by telephone; of the 21 patients who had received LRYGB, 10 (41.7%) were seen in the clinic and 11 (45.8%) could be reached only by telephone.

Early complications

Early complications were defined as those occurring <30 days postoperatively (Table 1). Of the 24 patients who received LRYGB, 1 (4.2%) required conversion to laparotomy because of a posterior leak diagnosed intraoperatively at the gastrojejunal anastomosis. An acute

Table 1
Early surgical complications

Group	Complication	Presentation time	Treatment	Hospital stay
LAGB	None	—	—	—
LRYGB	Posterior pouch leak	Intraoperative	Conversion to laparotomy and suture closure	6 d
	Jejunal perforation	3 d	Perforation suture; intestinal resection	6 mo

abdomen and sepsis were diagnosed 3 days after gastric bypass in one woman (47 years old; BMI 49 kg/m²). At laparotomy, proximal to the jejunojejunostomy, a jejunal perforation that resulted from an iatrogenic small bowel injury was found and treated by direct closure. The patient subsequently developed recurrent symptoms and sepsis and required a jejunal resection and small bowel anastomosis. She had a difficult postoperative period with a 6-month hospital stay. There were no early complications necessitating reoperation in the LAGB patients.

Reoperations

Band removal was performed in 9 of 22 (40.9%) LAGB patients, 5 of whom did not receive another bariatric procedure: 1 for band erosion, 3 for pouch dilation, and 1 for untreatable reflux symptoms caused by a large hiatal hernia. The treatment plans for 4 LAGB patients were converted to other bariatric procedures, LRYGB (n = 2) and biliopancreatic diversion (n = 2), for unsatisfactory weight loss. Port replacement was required in 1 of 23 (4.3%) patients.

Reoperations were performed in 6 of 21 (28.6%) LRYGB patients. One patient presented with small bowel obstruction 15 months after LRYGB. Diagnostic laparoscopy and subsequent laparotomy revealed a 30- to 40-cm segment of alimentary limb ischemia caused by an internal hernia. Small bowel resection was performed with an uneventful postoperative recovery. Cholecystectomy was required in 4

(19%) of the LRYGB patients for cholecystitis. One other patient developed an incisional hernia at the midline trocar site, requiring laparoscopic placement of an intraperitoneal dual-mesh prosthesis 72 months after the primary operation (Table 2).

LAGB patients who received band removal were excluded from weight loss analysis.

Therefore, 13 LAGB patients and 21 LRYGB patients were included in weight loss analysis.

Weight loss

At 10 years (range 120–130 months) after surgery, the patients in the LRYGB group had a significantly lower weight and BMI and a greater %EWL compared with those in the LAGB group (83 ± 18 kg versus 101 ± 22 kg, 30 ± 5 kg/m² versus 36 ± 7 kg/m² and 69 ± 29% versus 46 ± 27%, with *P* values of .002, .003, and .03, respectively) (Fig. 1–3). The lowest mean BMI of the obese patients was 28.9 kg/m² at 2 years after LRYGB versus 32.7 kg/m² at 2 years after LAGB. This increased to 30.4 kg/m² in LRYGB and to 35.7 kg/m² in LAGB at final analysis 10 years after surgery. There was weight regain from the lowest weight at approximately 2 years compared with 10 years in both groups. There was a mean weight regain in kg, BMI units, and %EWL of 6.5 ± 6.8 kg, 3 ± 3 kg/m², 10% ± 9% EWL, and 6.8 ± 7.4 kg, 2 ± 1 kg/m², 10% ± 11% EWL for LAGB group and LRYGB group respectively (*P* = NS).

In the LAGB group, 30.8% (4 of 13) of patients had EWL ≤ 25%, 23% (3 of 13) had EWL of 25% to 50%, and 46.2% (6 of 13) had EWL ≥ 50%. In the LRYGB group, 4.7% (1 of 21) of patients had EWL ≤ 25%, 19.1% (4 of 21) had EWL of 25% to 50%, and 76.2% (16/21) had EWL ≥ 50%.

In the LRYGB group, no statistically significant difference (*P* = .8, *t* test) was found in the %EWL for patients who were seen in the office (67.3%) and those reporting by telephone (67.1%). In LAGB group, no statistically significant difference (*P* = .8, *t* test) was

Table 2
Late surgical complications and reoperations

Group	Complication	Presentation time	Treatment	Hospital stay
LAGB	GPD	24 mo	Band removal	2 d
	GPD	36 mo	Band removal	3 d
	GPD	64 mo	Band removal	4 d
	GPD	84 mo	Band removal	4 d
	Band erosion	72 mo	Band removal	7 d
	Untreatable reflux symptoms	115 mo	Band removal, hiatal hernia repair	5 d
LRYGB	Internal hernia	15 mo	Intestinal resection	11 d
	Gallstones	64 mo	Cholecystectomy	4 d
	Gallstones	80 mo	Cholecystectomy	4 d
	Gallstones	102 mo	Cholecystectomy	4 d
	Gallstones	120 mo	Cholecystectomy	3 d
	Incisional hernia on trocar site	115 mo	Incisional hernia repair	4 d

GPD = gastric pouch dilation; LAGB = laparoscopic adjustable gastric banding; LRYGB = laparoscopic roux-en-y gastric bypass.

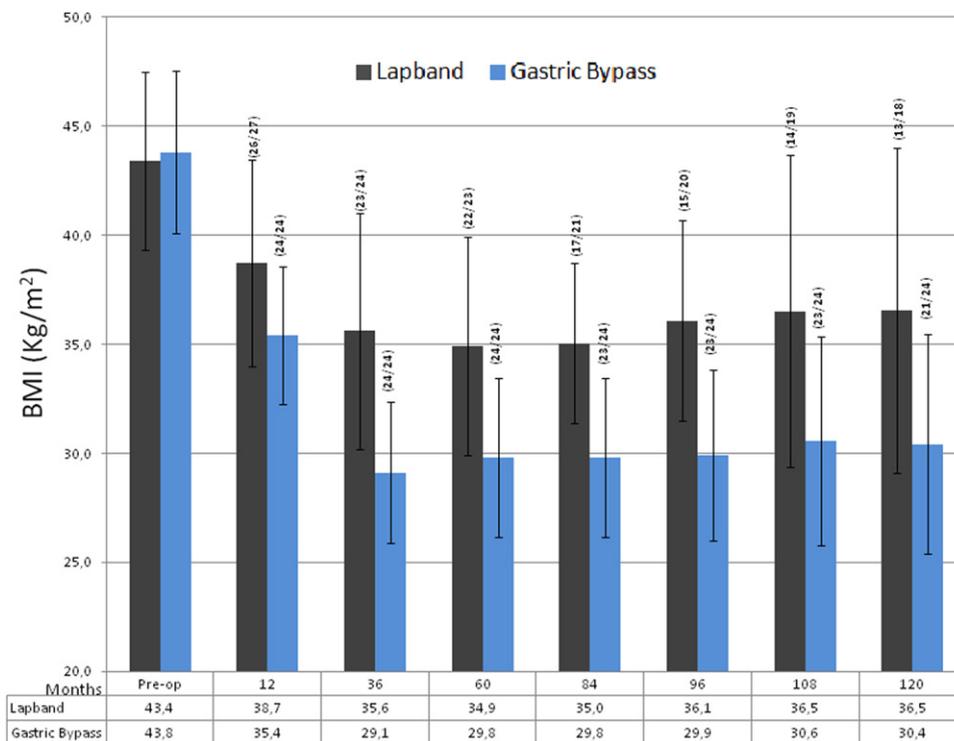


Fig. 1. Comparison of body mass index (BMI) between laparoscopic adjustable gastric banding (LAGB) and laparoscopic gastric bypass (LRYGB) group during 10 years of follow-up ($P = .003$ at 10 years). In brackets: n° of patients present at follow-up/n° of eligible patients.

found in the %EWL for patients who were seen in the office (48.4%) and those reporting by telephone (51.1%).

“Primary” failure (patients who never presented during 10 years of follow up with a BMI <35 kg/m²) was observed in 3 of 6 (50%) LAGB patients. All LRYGB

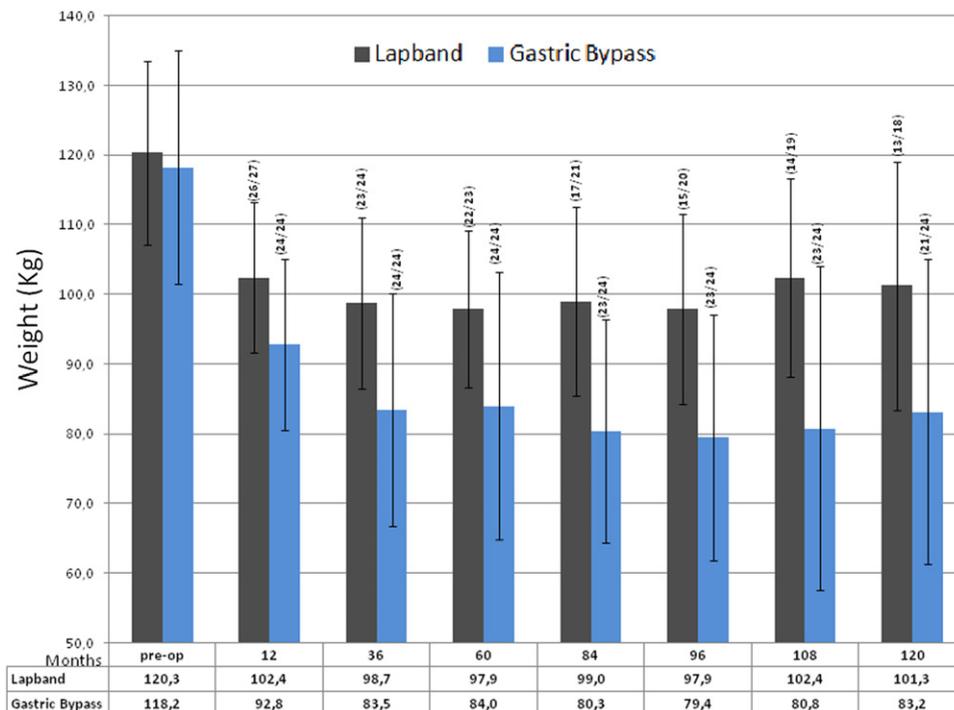


Fig. 2. Comparison of weight between laparoscopic adjustable gastric banding (LAGB) and laparoscopic gastric bypass (LRYGB) group during 10 years of follow-up ($P = .002$ at 10 years). In brackets: n° of patients present at follow-up/n° of eligible patients.

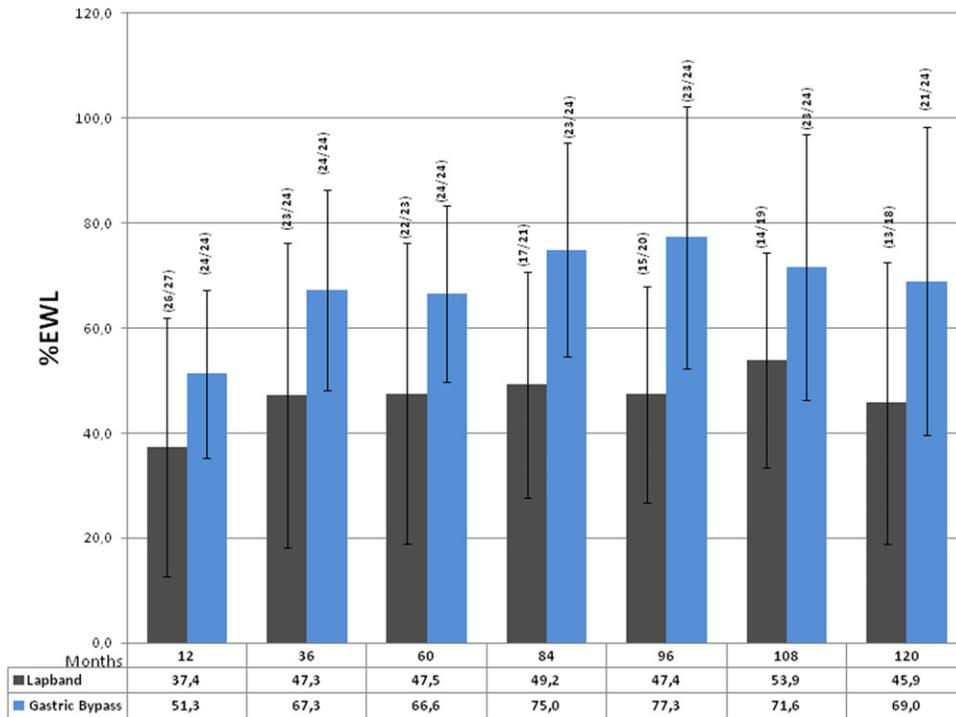


Fig. 3. Comparison of percentage of excess weight loss (%EWL) trend between laparoscopic adjustable gastric banding (LAGB) and laparoscopic gastric bypass (LRYGB) groups during 10 years of follow-up ($P = .003$ at 10 years). In brackets: n° of patients present at follow-up/ n° of eligible patients.

patients who presented with a BMI $> 35 \text{ kg/m}^2$ at 10 years experienced weight regain. Basically, all of the LRYGB patients reached BMI $< 35 \text{ kg/m}^2$ at their nadir point.

LAGB patients who received band removal without any other bariatric procedure experienced a substantial weight regain at 10 years. They presented with a mean weight (kg), BMI (kg/m^2), EWL% of 105.6 ± 15 , 39.1 ± 5.9 , and 34.9 ± 19.9 , respectively. Patients in the LAGB group whose treatment plans were converted to LRYGB ($n = 2$) had a BMI of 30 and 38.9 kg/m^2 at 10 years, respectively. Two patients underwent band removal and were then reassigned to undergo biliopancreatic diversion. One experienced excellent weight loss (BMI 28.7 kg/m^2) but suffered from severe life-endangering protein malnutrition and diarrhea and underwent reversal of the procedure. This patient actually had a preoperative BMI of 50 kg/m^2 . The other patient was lost at follow-up.

Nutritional supplementation compliance was 33%: only 7 of 21 LRYGB patients reported that they were regularly taking multivitamin tablets at 10 years. Of the remaining 14, only 3 female patients were taking oral and intravenous iron medication for intermittent anemia.

Co-morbidities

The patients were screened preoperatively for the presence of co-morbidities (diabetes, hypertension, and cardiac disorders). In the LAGB group, 3 patients had hypertension and 1 had sleep apnea. In the LRYGB group, 2 patients had

hyperlipidemia, 1 had hypertension, and 1 had T2DM. Of the 5 patients who returned at 10 years for office evaluation (2 of whom were affected by hypertension, 1 by T2DM, 1 by hyperlipidemia, and 1 by sleep apnea), hypertension, T2DM, hyperlipidemia, and sleep apnea were in remission.

Discussion

The use of laparoscopic obesity surgery is growing worldwide, with increasing demand from the patients. Two of the most commonly performed procedures are LAGB and LRYGB, although sleeve gastrectomy has recently increased in popularity. At the beginning of the third millennium, LAGB was the procedure of choice in Europe and was introduced in the United States in 2001 [8–13]. Similarly, LRYGB was the procedure of choice in the United States but has become more popular in Europe [8–13]. Our 10-year prospective, randomized study was undertaken at the beginning of our learning curve for LRYGB. However, we considered the design of this trial at a time in our experience when there was a minimum of surgeon and patient bias [14]. The perigastric band positioning technique for LAGB was switched to the pars flaccida approach to reduce band slippage, pouch dilation, and intragastric migration. The LRYGB technique was modified from that of Potvin et al. [15], with meticulous pouch calibration and limb length measurement [16].

There are only 2 prospective, randomized trials comparing LAGB and LRYGB: the first one was published by our

Table 3

Studies comparing laparoscopic adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass

Author	Arm	N	Age	BMI	FU, y	FU rate %	Mean end-study BMI	Mean end-study %EWL	%Weight loss Failure		Band reoperation rate %
									BMI >35	EWL <50%	
Christou (2009)	LAGB	149	42.3	45	3–5	72 (3 y)	31.7 (3 y)	61	33 (3 y)	38 (3 y)	12.7
	LRYGB	886	40.1	50.9	3–5	62 (3 y)	30.4 (3 y)	75.2	22 (3 y)	9 (3 y)	
Boza (2010)	LAGB	62	38.4	35.8	5	91.9	29.8	59.1	—	45.6	9.6
	LRYGB	91	34.5	39.6	5	73.6	26.5	92.9	—	6	
Campos (2011)*	LAGB	100	47	45.7	1	93	36	36	—	69 [§]	5.3
	LRYGB	100	47	46	1	92	30	64	—	7 [§]	
Spivak (2012)	LAGB	127	42.1	45.9	7–10	33.8 (7 y)	—	38.1–46.3	—	28.2 [‡]	23
	LRYGB	105	40.6	48.2	7–10	72.7 (7 y)	—	58.5–75.6	—	0 [‡]	
Romy* (2012)	LAGB	221	—	43~	6	92.8	32.5~	50~	33.5	—	22.2
	LRYGB	221	—	43~	6	91.9	30~	62.5~	12.3	—	
Angrisani [†] (2012)	LAGB	27	33.3	43.4	10	81.4	36	46	46.2	—	40.9
	LRYGB	24	34.7	43.8	10	87.5	30	69	19	—	

BMI = body mass index; %EWL = percentage of excess weight loss; FU = follow-up.

*Pair-matched studies.

†Prospective, randomized trial.

‡EWL < 25%.

§EWL < 40%.

||Port-related complication excluded.

group in 2007 (5-year follow-up) [6], and the other one was by Nguyen et al. in 2009 [17] (4-year follow-up). Nguyen et al. [17] reported that gastric bypass resulted in better weight loss at medium (2–3 years) and long-term (4 years) follow-up but was associated with more perioperative and late complications and a higher 30-day readmission rate compared with LAGB. EWL was 68.4% in the LRYGB group and 45.4% in the LAGB group at 4 years. Moreover, male gender and a BMI >50 kg/m² were found to be predictive factors of poor weight loss in patients who underwent LAGB. This trial was larger than our study, but it had significant differences in baseline BMI and age, a poor ratio of recruitment to enrollment, and an unusual gastrojejunostomy stricture rate of 15.3%. Most series have stricture rates ranging from 4% to 8% at most. In our study, no patient in LRYGB group had suffered from stenosis at the gastrojejunostomy site. One possible explanation is that at the time of intraoperative leak diagnosis, 3-0 absorbable suture (Vicryl, Ethicon Inc., Norderstedt, Germany) was constantly used, differently from the majority of surgeons who prefer nonabsorbable silk suture. Differently from Nguyen et al. (who used a 21-mm circular stapler at the beginning of his trial), we have always (during the last 12 years in >500 cases) performed a 25-mm circularly stapled gastrojejunostomy (unpublished data) with minimal incidence of leak and stenosis.

An extensive review of the international literature of comparative studies regarding LAGB versus LRYGB up to 2007, was published by Tice et al. [18]. The authors concluded that despite the widespread marketing of LAGB, no subgroups have been identified in whom it performs

better than gastric bypass. Most of the studies analyzed were judged of very low quality. The authors concluded that gastric bypass should remain the primary procedure used for the treatment of obesity. Of the 14 papers included in Tice et al.'s systematic review, in only 6 were we able to find both LAGB reoperation rate and follow-up length; LAGB reoperation rate varies from 14% to 27% in a follow-up range from 12 to 60 months.

Subsequently to Tice et al.'s publication, a few comparative retrospective studies analyzing patients who underwent LAGB or LRYGB appeared in the international literature, and they are summarized in Table 3. Romy et al. [19], from the Michel Suter group in Switzerland, in a case-matched study of 442 patients (follow-up rate 92.3% at 6 years), concluded that LRYGB was associated with better weight loss, resulting in a better correction of some co-morbidities than LAGB, but at the price of a higher early complication rate. This difference, however, is largely compensated by the much higher long-term complication and reoperation rates seen after LAGB. Campos et al. [20] compared complications and 1-year outcomes of RYGB and LAGB in 200 pair-matched morbidly obese patients, with >90% follow-up. They found that RYGB had a higher rate of perioperative complications, a similar rate of overall complications (11% versus 14%), and a lower rate of reoperations compared with LAGB. At the end of the first year, patients who had undergone RYGB had greater excess weight loss (64% versus 36%), more resolution of diabetes, and better quality of life than those who underwent LAGB. Among the retrospective comparative studies, Spivak et al. [21] published long-term outcomes (10-year

Table 4
Single-series laparoscopic adjustable gastric banding studies with long-term follow-up (≥ 5 years)

Author	N	Age	BMI	FU, y	FU rate %	Mean end-study BMI	Mean end-study %EWL	%Weight loss failure		Band removal %	Erosion %	Slipped/pouch %	
								BMI >35	EWL >50%				
Suter (2006)	317	Perigastric/pars flaccid	38.5	43.5	7	81.5	30–31 ca	59 (5 y)	—	43	21.7	9.5	6.3
Favretti (2007)	1791	Perigastric/pars flaccida	38.7	46.2	10	91.3	37.7 \pm 9.1	35.4 \pm 29.6	—	—	5.9	0.9	3.9
Tolonen (2008)	123	Pars flaccid	43	49.28	7	70	—	55.7	—	55.7	13.8	3.3	6.5
Mittermair (2009)	785	Pars flaccid	38	42.9	8	43.3 (6 y)	29.8 (6 y)	57.4 (6 y)	—	37.8 (6 y)	7.3 (18.1)*	6.5	15.29 [†]
Boza (2010)	199	Pars flaccid	37.8	36	5	95	29.9	58.4	—	46.3	14	0.5	6
Himpens (2011)	82	Perigastric	50	41.57	12	54.3	33.79	48	—	—	50	29.3	10.9
Alhamdani (2012)	575	Pars flaccid	43	47	5	85.7	—	40	—	—	10.4	0.3	4.8

BMI = body mass index; %EWL = percentage of excess weight loss; FU = follow-up.

*Total percentage of band removal, change or repositioning.

[†]Total rate of complication excluding port-related problems = 39.4% (esophagitis, esophageal dilation, pouch dilation, band migration, and band leakage; 20.5% of which requiring major reoperation).

follow-up) for LAGB and LRYGB. This study reported that LRYGB was associated with significantly and persistently better weight loss (58.6% versus 46.3% EWL at 7 years) and a lower failure rate (10.7% versus 51% at 10 years) than LAGB. However, this favorable outcome was accompanied by a few serious life-threatening complications in LRYGB group. Boza et al. [22] reported an excellent 59.1% EWL for LAGB (n = 62) and 92.9% EWL for LRYGB (n = 91) during a 5-year follow-up period. Late reoperations were necessary for 9.9% of the LRYGB patients and 24.1% of the LAGB patients. The authors concluded that LRYGB was a better weight loss procedure than LAGB. Christou and Efthimiou [23] followed 886 LRYGB and 146 LAGB patients. At 5 years, they had data on 40 LRYGB patients and only 10 LAGB patients; the %EWL for these groups were 75.2% and 61%, respectively. At 3 years, however, they had data on 153 LRYGB and 38 LAGB patients, and the %EWL for these patients were 79.2% and 58.6%, respectively.

As we can clearly notice from the aforementioned data, authors reported significantly better long-term weight loss

results and lower rate of revisional surgery in LRYGB groups. The encouraging long-term results of LAGB (5-year follow-up) presented by Christou and Efthimiou have many limitations, including mainly the very small sample size of patients in LAGB group available at follow-up. Three years data reflect better those available in international literature.

Noncomparative, retrospective, single-case series offer longer term follow-up data (Table 4 and 5). In 2006, Suter et al. [24] presented their results after up to 8 years (mean 74 months) of follow-up of prospectively collected data of patients who underwent LAGB between 1997 and 2003. In this series, EWL was <50% in 33.6% of these patients after 5 years and 43% after 7 years. Similarly, insufficient weight loss (EWL <25%) occurred in 10.5% of these patients after 5 years and in 14% after 7 years. When the overall results are considered, Suter clearly stated that the incidence of failure (EWL <25% or band removal) increased constantly over time from 13.2% after 18 months (best mark) to 36.9% after 7 years. The success rate (EWL >50%) was maximal after 24 months at 53.8%, but declined progressively to 42.9% after 7 years. Overall

Table 5
Single-series Roux-en-Y gastric bypass studies with long-term follow-up (≥ 10 years)

Author	N	Age	BMI	FU, y	FU rate %	Lowest BMI	Mean end-study BMI	Higher %EWL	Mean end-study %EWL	%Weight loss failure		Internal hernia %	GJ stenosis%
										BMI >35	EWL <50%		
Christou (2006)	272 (laparotomy)	—	48.1	11.4 (mean)	83.8	28.6	33.6	88.6	67.6	35*	—	—	—
Higa (2010)	242 (laparoscopy)	—	—	10	26	29.9	33	68.6	57	—	33.2	16	4.9
Edholm (2012)	384 (laparoscopy)	37.9	44.5	11	71.2	—	32.5	92.9 [†]	63.3 [†]	—	30 [†]	5	—

BMI = body mass index; %EWL = percentage of excess weight loss; FU = follow-up; GJ stenosis = gastrojejunal stenosis.

*Morbidly obese failure rate 20%; super-obese failure rate 58%. No statistically significant difference between short and long-limb operations.

[†]Excess body mass index loss (EBMIL).

complication rate was 33.1%. Therefore, the authors stated that LAGB should no longer be considered as the procedure of choice for severe obesity because of poor results in terms of long-term excess weight loss and high rates of long-term complications. Himpens et al. [25], in their study of long-term outcomes of LAGB (follow-up rate 54.3 at 12 years), observed a mean EWL of 42.8% and a satisfaction rate of 60.3%. However, almost 1 of 3 patients experienced band erosion (28%) and close to 50% of them required band removal. The authors stated that LAGB had an excessive high long-term failure rate. Favretti et al. [26] reported 12 years of LAGB experience, showing a mean 8.5 kg/m² reduction in BMI and only a 2.3% rate of lost bands. The authors suggested that LAGB be considered the primary weight loss procedure. Tolonen et al. [27] reported 55.7% EWL during a 7-year follow-up period and 53.1% EWL during an 8-year follow-up period for their LAGB patients. Using a method similar to ours, they found a failure rate of 44.2% during an 8-year follow-up period but concluded that LAGB should be one of the accepted surgical tools for weight loss. Mittermair et al. [28], in their study, observed that 785 morbidly obese patients who underwent placement of the Swedish adjustable gastric band had a median change in weight of -26 kg at 1 year and -40.5 kg at 8 years after the surgery (follow-up rate 93.4% at 8 years), corresponding to a median change in weight from preoperatively 120 kg to 79.5 kg after 8 years. The %EWL was 40.4% after 1 year and 65.5% after 8 years, and BMI fell from 42.9 to 28.3 kg/m² after 8 years. Nevertheless, 32% of patients required a reoperation. The authors stated that LAGB requires a high degree of patient cooperation, including major modifications in lifestyle and eating habits, as well as professional support during follow-up. Our data in terms of LAGB revision rate and insufficient weight loss compare quite favorably with those reported from different authors analyzing long-term outcomes of LAGB, with the exception of Favretti et al. [26].

Although Roux-en-Y gastric bypass was introduced in the United States by Mason and Ito [29] >40 years ago, a few 10-year follow-up studies have been recently published in the international literature. A retrospective review of a prospectively collected database was published by Higa et al. [30] in 2011 in which they presented 10-year follow-up results with LRYGB and stated that this procedure provided long-term weight loss and resolution of comorbidities, despite difficulties in collecting long-term data (10-year follow-up rate: 26%). Their mean excess weight loss was 57% at 10 years, and 33.2% of patients failed to achieve an excess weight loss of at least 50%. Among these patients, 8.7% experienced weight regain, the remaining being primary failure. Internal hernia rate was remarkably high (16%), and the gastrojejunal stenosis rate was 4.9%. Edholm et al. [31] observed that RYGB produced good and sustained long-term weight loss, excess BMI loss (EBMIL) of 63.3% at 11 years, and lasting improvement in comorbidities, combined with high patient satisfaction (79%).

The need for revisional surgery was small (2.1%), although the adherence to supplementation was disturbingly low. In their retrospective single-case series, Christou et al. [32] reported results about weight gain after short- and long-limb gastric bypass in patients followed for longer than 10 years. All operations were performed by open laparotomy. There was a significant ($P < .0001$) increase in BMI in both morbidly obese (BMI < 50 kg/m²) and super-obese patients (BMI > 50 kg/m²) from the nadir to 5 years and from 5 to 10 years. The super-obese lost more rapidly from time zero and gained more rapidly after reaching the lowest weight at approximately 2 years than the morbidly obese patients. There was no difference in results between the long- and short-limb operations, and there was a significant increase in failure and decrease in excellent results at 10 years compared with 5 years. The failure rate when all patients were followed for at least 10 years was 20% for morbidly obese patients and 58% for super-obese patients. Recently a meta-regression study was published by Attiah et al. [33] to assess durability of RYGB performed with both laparoscopic and open technique. Twenty-two reports with a total of 4206 patient cases were included. An inverse variance weighted model and meta-regression were used to generate the pooled percent mean EWL and the durability of EWL over time. Pooled mean EWL was 66.5% (mean follow-up of 3.6 years), and there was no significant association between EWL and length of follow-up. According to the authors, these findings provide support for the overall durability of RYGB in aggregate. It is quite clear that durability of weight loss after gastric bypass cannot be evaluated on a follow-up limited to 3–5 years. In our experience, 19% of LRYGB patients presented weight regain, confirming 10-year follow-up data from Christou et al. and Higa et al.

Our 10-year results of LRYGB patients are similar to those reported in the aforementioned single-case series. Weight regain and lack of compliance to long-term supplementation therapy appear to be most relevant problems of this operation.

One of the limitations of this study was the small patient sample for the 2 groups. Another potential limitation is the criteria of success, which has been the same (EWL ≥ 50%) for 2 operations that are entirely different in term of anatomic and metabolic consequences. LRYGB is much more effective and aggressive and certainly carries much higher risk of morbidities and mortality than LAGB. Moreover, it is important to underline and state clearly that approximately 1 out of 2 patients could be reached only by telephone, thus giving us data about self-reported weight and remission of co-morbidities.

Conclusion

For morbidly obese patients with BMI > 35 and < 50 kg/m², LRYGB was unquestionably superior to LAGB in terms of excess weight loss results (%EWL ≥ 50%: 76.2% versus 46.2%, respectively) at 10 years. However, LRYGB exposes patients to higher early complication rates than

LAGB (8.3% versus 0%) and potentially lethal long-term surgical complications (internal hernia and bowel obstruction rate: 4.7%). Long-term nutritional consequences of LRYGB remain poorly studied. Only 33% of patients in this series were still taking vitamin and iron supplements. Although limited to 20% of the study population at 10 years, weight regain after LRYGB will probably increase progressively over time and certainly represent an area of potential improvement. LAGB, with its revision rate of 40.9% in the morbidly obese population, could be considered only for a scheduled multiphase surgical strategy informing the patients of the high possibility of reoperation and conversion to other procedures. The use of LAGB should be consistently explored in patients suffering from a less advanced stage of disease: class I obesity (BMI < 35).

Disclosure

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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